IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* DAVID M. KESTER, STATE OF CALIFORNIA *ex rel.* DAVID M. KESTER, STATE OF COLORADO *ex rel.* DAVID M. KESTER, STATE OF CONNECTICUT *ex rel.* DAVID M. KESTER, STATE OF DELAWARE *ex rel.* DAVID M. KESTER, DISTRICT OF COLUMBIA *ex rel.* DAVID M. KESTER, STATE OF FLORIDA *ex rel.* DAVID M. KESTER, STATE OF GEORGIA *ex rel.* DAVID M. KESTER, STATE OF HAWAII *ex rel.* DAVID M. KESTER, STATE OF ILLINOIS *ex rel.* DAVID M. KESTER, STATE OF INDIANA *ex rel.* DAVID M. KESTER, STATE OF LOUISIANA *ex rel.* DAVID M. KESTER, STATE OF MARYLAND *ex rel.* DAVID M. KESTER, STATE OF MASSACHUSETTS *ex rel.* DAVID M. KESTER, STATE OF MICHIGAN *ex rel.* DAVID M. KESTER, STATE OF MINNESOTA *ex rel.* DAVID M. KESTER, STATE OF MONTANA *ex rel.* DAVID M. KESTER, STATE OF NEVADA *ex rel.* DAVID M. KESTER, STATE OF NEW JERSEY *ex rel.* DAVID M. KESTER, STATE OF NEW MEXICO *ex rel.* DAVID M. KESTER, STATE OF NEW YORK *ex rel.* DAVID M. KESTER, STATE OF NORTH CAROLINA *ex rel.* DAVID M. KESTER, STATE OF OKLAHOMA *ex rel.* DAVID M. KESTER, STATE OF RHODE ISLAND *ex rel.* DAVID M. KESTER, STATE OF TENNESSEE *ex rel.* DAVID M. KESTER, STATE OF TEXAS *ex rel.* DAVID M. KESTER, STATE OF VIRGINIA *ex rel.* DAVID M. KESTER, and STATE OF WISCONSIN *ex rel.* DAVID M. KESTER, **Plaintiffs, **v.** **NOVARTIS PHARMACEUTICALS CORPORATION, ACCREDO HEALTH GROUP, INC., AMERISOURCE BERGEN CORPORATION, BIOSCRIP CORPORATION, CURASCRIPT, INC., CVS CAREMARK CORPORATION, EXPRESS SCRIPTS,**	**FIRST AMENDED COMPLAINT** **CIVIL ACTION No. 11-8196 (McMahon, J.)** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)** **JURY TRIAL REQUESTED**

MEDCO HEALTH SOLUTIONS, INC. and WALGREENS COMPANY,)
)
)
Defendants.)

FIRST AMENDED COMPLAINT
(False Claims Act)

SUMMARY STATEMENT

1. This lawsuit involves a scheme by Defendant Novartis Pharmaceuticals Corporation ("Novartis"), one of the largest manufacturers of pharmaceutical products in the world, to pay kickbacks to owners of specialty pharmacy chains, including Defendants Accredo Health Group, Inc. ("Accredo"), Amerisource Bergen Corporation ("Amerisource"), BioScrip Corporation ("Bioscrip"), Curascript, Inc. ("Curascript"), CVS Caremark Corporation ("Caremark"), Express Scripts, Inc. ("Express Scripts"), Medco Health Solutions, Inc. ("Medco") and Walgreens Company ("Walgreens"), to induce those pharmacies to recommend that patients order Novartis specialty medications reimbursed by federal and state health care programs, including, but not limited to, the drugs Gleevec, Exjade, Tasigna, Tobramycin Inhalation Solution (TOBI), and Myfortic.

2. In Novartis' own words, the pharmaceutical manufacturer seeks to "leverage" the "[r]ole of key influencers such as Specialty Pharmacies." Novartis "leverages" specialty pharmacies by offering them financial inducements, such as referrals of patients from Novartis' reimbursement hubs and "rebates" or "discounts" pegged to the pharmacy's "performance" in achieving Novartis' sales goals, in exchange for the specialty pharmacies' agreement to use pharmacists, nurses and other staff—perceived as objective and acting in the best medical

interests of patients—to recommend and increase the sales of Novartis specialty drug products and to take steps to capture an increased market share for Novartis' products.

3. Novartis' scheme exploits for its own corrupt purposes the special trust that patients place in their pharmacists. Patients rely on the expertise and objectivity of their pharmacists when seeking advice on whether to order, refill, discontinue or change medications. Unbeknownst to these patients, and to the public at large, Novartis has corrupted the objectivity of the specialty pharmacies with whom they do business by rewarding those pharmacies with financial compensation for increasing orders of Novartis medications. This illegal financial compensation induces pharmacists to increase sales of drugs that are often more expensive for payers, and less efficacious and safe, than other drugs sold by the competition. Neither Novartis nor the specialty pharmacies that participate in this scheme disclose to patients or physicians that the pharmacists are receiving financial inducements.

4. Publicly-funded health care programs do not cover medications ordered as a result of the payment of kickbacks.

5. As a result of this scheme, Defendant Novartis knowingly caused specialty pharmacies, including Defendants Accredo, Amerisource, Bioscrip, Curascript, Caremark, Express Scripts, Medco and Walgreens, to submit hundreds of millions of dollars in false claims to publicly-funded health care programs for specialty medicines, including Gleevec, Exjade, Tasigna, TOBI, Myfortic, and others, that were ordered as a result of kickbacks.

6. As a result of this scheme, Defendants Accredo, Amerisource, Bioscrip, Curascript, Caremark, Express Scripts, Medco and Walgreens, and the other specialty pharmacies with which Novartis conspired, also acted knowingly in submitting hundreds of

millions of dollars in false claims to publicly-funded health care programs for medicines that were ordered as a result of kickbacks. In addition, Defendant Caremark acted knowingly in causing the submission of false claims by the specialty pharmacies to which Caremark's Theracom unit steered patients; and Defendant Amerisource acted knowingly in causing the submission of false claims by the specialty pharmacies to which Amerisource's LASH group steered patients.

7. *Qui Tam* Plaintiff David M. Kester ("Kester" or "Relator"), a Respiratory Account Manager II for Defendant Novartis Pharmaceuticals Corporation, brings this civil action on behalf of and in the name of the United States of America ("United States") under the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. §§ 3729-3733, and on behalf of and in the name of the state plaintiffs under analogous *qui tam* provisions in state false claims laws.

JURISDICTION AND VENUE

8. All Counts of this Complaint are civil actions by Relator, acting on behalf of and in the name of the United States and the state plaintiffs, against the Defendants under the federal False Claims Act, 31 U.S.C. §§ 3729-3733, and analogous state false claims laws.

9. This Court has jurisdiction over the claims brought on behalf of the United States pursuant to 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. § 3732(a).

10. This Court has jurisdiction over the state law claims alleged herein under 31 U.S.C. § 3732(b). In addition, the Court has supplemental jurisdiction over the claims brought on behalf of the state plaintiffs under 28 U.S.C. § 1367.

11. The False Claims Act provides that an action under 31 U.S.C. § 3730 may be brought "in any judicial district in which . . . any one defendant can be found, resides, transacts

business, or in which any act proscribed by section 3729 occurred." 31 U.S.C. § 3732(a). The Defendants all transact business in this judicial district by, among other things, shipping specialty medications to customers residing in this judicial district. Indeed, the Borough of Manhattan is a large market for the specialized medications at issue in this complaint. Moreover, Defendant BioScrip owns and operates a pharmacy in Manhattan and has its corporate headquarters in this judicial district. Accordingly, this Court has personal jurisdiction over the Defendants, and venue is appropriate in this district. 31 U.S.C. § 3732(a). Venue is also proper under 28 U.S.C. § 1391.

12. None of the allegations set forth in this Complaint is based on a public disclosure of allegations or transactions in a criminal, civil or administrative hearing, in a congressional, administrative or General Accounting Office report, hearing, audit or investigation, or from the news media. Relator David M. Kester has direct and independent knowledge of the information on which the allegations set forth in this Complaint are based. Moreover, prior to filing this lawsuit and prior to any public disclosures regarding this matter, Relator voluntarily provided the information set forth herein to agents of the United States Department of Justice.

13. None of the allegations or transactions set forth in this Complaint is substantially the same as allegations or transactions that have been publicly disclosed in a Federal criminal, civil or administrative hearing in which the Government or its agent is a party, or in a congressional, administrative or Government Accountability Office, or other Federal report, hearing, audit or investigation, or from the news media.

THE PARTIES

Relator David M. Kester

14. David Kester was born in Atlanta, Georgia. He received a Bachelor of Arts Degree in Chemistry from the University of North Carolina at Chapel Hill in 1981. Since then, he has worked in the area of sales and marketing for industrial chemical and pharmaceutical manufacturers. He has received multiple awards and repeated recognition for outstanding performance during his career. For example, Morton Thiokol, Inc. named him Salesman of the Year in 1989 and 1990; Pharmacia recognized that he was 3rd of 23 managers in sales growth in 2003; and Chiron Corporation Biopharmaceuticals ranked him 7th in its President's Club Ranking in 2004 and 3rd in its Presidents Club Ranking through May 2005.

15. Relator was hired by Defendant Novartis in 2006 as an Area Sales Manager I. He subsequently worked for Novartis as an Area Sales Manager II with responsibility for managing nine sales representatives in North Carolina, Virginia, West Virginia, Maryland, South Carolina, Georgia, Florida, Alabama, Mississippi, Tennessee, Louisiana, Texas, Oklahoma, Arkansas, and Kentucky, who are assigned to market the cystic fibrosis drug Tobramycin Inhalation Solution ("TOBI"). From September 6, 2012, he has held the position of Respiratory Account Manager II. Beginning with his first full calendar year at the company, Novartis repeatedly has recognized Relator's exceptional management and sales ability. In 2007, he received the company's "Impact Award," an honor reserved for those managers who possess the confidence, competence, and accountability that impacts the productivity of one's team and drives results. In 2008, he received both the "Impact Award" and the President's Club Award for a Top Area; the latter is given to the manager with the highest area sales attainment versus

goal for the year. In 2009, he was promoted. In 2010, he once again received the President's Club Award for a top area. On April 12, 2013, Relator resigned from his employment at Novartis, effective April 19, 2013.

16. During his tenure at Novartis, Relator has spoken up about Novartis practices that he felt were improper or illegal on a number of occasions. Each time, he has suffered retaliation as a result. In August 2010, Relator voiced concerns through an intermediate-level manager to a Novartis vice president about whether a sales pitch proposed by the vice president might be "off-label" and thus illegal. In response, the vice president challenged him in front of the entire sales team the next morning and aggressively disagreed with his position. In addition, despite record sales accomplishments in 2010, his merit raise in February 2011 was the lowest since he joined Novartis. The company provided an explanation that made no logical sense. Relator has not raised the matters alleged herein with company management because he is certain that his doing so would not lead to changes in practices, but rather would result in his facing serious retaliatory measures, such as actual or constructive discharge.

17. Relator lives in Raleigh, North Carolina.

Plaintiff United States Of America

18. Relator David Kester brings this action on behalf of the United States pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. § 3729 *et seq*.

19. On behalf of the United States, Relator seeks recovery for damages to federally-funded health insurance programs, including, but not limited to, the federal-state Medicaid drug benefit program, established under Title XIX of the Social Security Act, 42 U.S.C. §1396 *et seq*, and state laws; the Medicare Part D program, established under Title XVIII of the Social

Security Act, 42 U.S.C. §§ 1395w-101 through 1395w-154; the Federal Employees Health Benefits Plan ("FEHBP"), established under Chapter 89 of Title 5 of the U.S. Code, 5 U.S.C. §§ 8901 through 8914; and the U.S. Department of Defense TRICARE and CHAMPUS health care programs, established pursuant to 10 U.S.C. § 1071 *et seq*.

20. The Centers for Medicare and Medicaid Services ("CMS") of the U.S. Department of Health & Human Services ("HHS") funds and oversees the joint federal-state funded Medicaid Program for the financially needy. The state plaintiffs participate in the Medicaid program, under which they pay for pharmaceutical drugs in certain circumstances and for certain indigent individuals who are beneficiaries of such programs. Reimbursement for drugs covered by a state Medicaid program is made by each state's Medicaid program agency, which, in turn, seeks reimbursement for a portion of its expenditures from the federal government.

21. CMS funds and oversees the Medicare Part D program, which covers a portion of prescription drug expenses for individuals eligible for traditional Medicare who have voluntarily enrolled in a Part D plan. The enrollee must pay plan premiums, co-payments and co-insurance, and a deductible. In addition, the enrollee must pay 100% of his or her prescription drug expenditures when those expenditures for the year fall within a specified financial bracket (the so-called "donut hole").

22. The U.S. Office of Personnel Management ("OPM") funds and oversees the FEHBP, which covers a portion of prescription drug expenditures incurred by federal government employees and their families.

23. The U.S. Department of Defense ("DOD") funds and oversees the CHAMPUS and TRICARE programs, which cover a portion of prescription drug expenditures incurred by civilian DOD employees.

State Plaintiffs

24. Relator brings this action on behalf of the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia and Wisconsin, and the District of Columbia ("the state plaintiffs"). He brings this action under the *qui tam* provisions of the following false claims laws of the state plaintiffs: California False Claims Law, Cal. Gov. Code § 12650 *et seq.*; Colorado Medicaid False Claims Act, Col. Rev. Stat. 25.5-4-303.5 through 25.5-4-310 (2010); Conn. Gen. Stat. § 17b-301d (2010); Delaware False Claims and Reporting Act, 6 Del. C. § 1201 *et seq.*; Florida False Claims Act, Fla. Stat. §§ 68-081-68.09; Georgia State False Medicaid Claims Act, Georgia Code, Title 49, Ch. 4, Art. 7B; Hawaii False Claims Law, HRS § 661-21 *et seq.*; Illinois Whistleblower Reward & Protection Act, 740 ILCS 175/1 *et seq.*; Indiana False Claims & Whistleblower Protection Law, Ind. Code § 5-11-5.5.-1 *et seq.*; Louisiana Qui Tam Action Act, La. R.S. 46:438:3 *et seq.*; Maryland False Health Claims Act, Md. Health-Gen. Code Ann. §§ 2-601 through 2-611 (2010); Massachusetts False Claims Law, ALM Ch. 12 § 5A-0 *et seq.*; Michigan Medicaid False Claims Act, Mich. Code 400.601 *et seq.*; Minnesota False Claims Act, Minn.Stat. § 15C.01 *et seq.*; Montana False Claims Act, Mon. Code Anno. § 17-8-401 *et seq.*; Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. § 357.010 *et seq.*; the New Jersey False Claims Act, N.J.

Stat. § 2A:32C-1 *et seq.*; New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*; New York False Claims Act, NY State Finance Law, Art. 13, § 187 *et seq.*; North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq*. (2010); Oklahoma Medicaid False Claims Act, 63 Okla. St. § 5053.1 (2011) *et seq.*; Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq*. (2010); Tennessee Medicaid False Claims Act, 71-5-181 through 71-5-185; Texas False Claims Act, Texas Human Resources Code, § 36.002 *et seq.*; Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*; Wisconsin False Claims for Medical Assistance, Wis. Stat. § 20.931; and the District of Columbia False Claims Act, D.C. Code § 2-308.14 *et seq*.

25. On behalf of the state plaintiffs, Relator seeks recovery for damages caused by the submission of false claims to state-funded health insurance programs, including but not limited to: i) the federal-state Medicaid programs that are jointly funded by the United States and the state plaintiffs; and ii) other state health insurance programs, such as New York's Program for Elderly Pharmaceutical Insurance Coverage, that cover some or all of the costs of prescription medication.

The Manufacturer Named As Defendant

Novartis Pharmaceuticals Corporation

26. Novartis Pharmaceuticals Corporation ("Novartis") researches, develops, manufactures and distributes medications. Novartis is owned, through a United States holding company, by Novartis International AG, a pharmaceutical manufacturer headquartered in Basel, Switzerland. Novartis' corporate headquarters in the United States are in East Hanover, New Jersey. In 2010, Novartis AG had total sales of $50.6 billion and net income of $3.4 billion, and it had 161,500 employees worldwide.

27. Novartis manufactures and sells a number of "specialty medications," *i.e.*, drugs that may be particularly costly or require special handling, administration or monitoring, and that are used to treat chronic, complex conditions.

The Specialty Pharmacies Named As Defendants

28. Novartis has entered into illegal kickback schemes with numerous entities that own specialty pharmacies or operate specialty pharmacy franchise programs. Relator names as defendants the six of those entities that handle the largest number of prescriptions of Novartis' specialty medications at issue in this First Amended Complaint, along with two of their corporate parents.

Accredo Health Group, Inc. & Medco Health Solutions, Inc.

29. Defendant Accredo Health Group, Inc. ("Accredo"), headquartered in Memphis, Tennessee, is a wholly-owned subsidiary of Defendant Medco Health Solutions, Inc. ("Medco"). Accredo is one of the largest specialty pharmacies and, as of 2010, was the largest mail order pharmacy in the United States. Through so-called Therapeutic Resource Centers, Accredo provides specialty pharmacy and related services for individuals with complex and chronic health conditions. According to the company's website, Accredo's "pharmacists and other healthcare professionals talk frequently with patients over the phone, helping them follow their treatment and educating them about their condition." Accredo further maintains on its website that its "therapy management consists of clinically based protocols developed for each of the medication categories for which we provide services. Accredo's clinical protocols help to provide optimal clinical outcomes for you, the patient." Accredo also assures drug manufacturers that the pharmacy engages in "[r]egular communication with physician offices" with pharmacy teams providing "regular updates to

physicians, alerting them to adherence issues, adverse events and other anomalies." Accredo dispenses approximately 200 specialty drugs from approximately 83 dispensing pharmacies nationwide.

30. Defendant Medco, headquartered in Franklin Lakes, New Jersey, is a provider of pharmaceutical services. In 2010, Medco was ranked # 35 on Fortune Magazine's list of the Top 500 companies; the company's 2010 net revenues were $66 billion. Medco publicly holds itself out as a provider of "clinically driven pharmacy services designed to improve the quality of care."

Amerisource Bergen Corporation

31. Defendant Amerisource Bergen Corporation ("Amerisource"), headquartered in Valley Forge, Pennsylvania, is one of the world's largest pharmaceutical services companies. In 2010, it earned $78 billion and ranked number 24 on the Fortune Magazine list of top 500 companies. The company handles 20% of the pharmaceutical drugs sold and distributed in the United States. Through its Specialty Group, including US Bioservices, it sells and distributes specialty medications. Through its "LASH" group, it partners with drug manufacturers to "prove market value and expand market access." The LASH group operates out of Charlotte, North Carolina.

BioScrip Corporation

32. Defendant BioScrip Corporation ("BioScrip") is headquartered in Elmsford, New York. BioScrip owns 34 specialty pharmacies across the country, including both community pharmacies and mail service facilities. The company specializes, among other things, in providing specialty pharmaceutical products for patients with chronic and acute health care conditions. BioScrip owns a community pharmacy located at 197 8th Avenue in New York, N.Y.

In its 2010 Annual Report, BioScrip states as follows: "[W]e proactively contact patients in instances of missed refills and alert physicians and other health care providers when the patient can't be located." The company boasts in its annual report that it achieves "higher compliance rates [*i.e.*, taking medications properly] as compared to industry averages and other documented and available metrics [*i.e.*, refill rates]."

Curascript, Inc. and Express Scripts, Inc.

33. Defendant Curascript, Inc. ("Curascript"), a wholly-owned subsidiary of Defendant Express Scripts, Inc., is a specialty pharmaceutical services company headquartered in Orlando, Florida. The company supplies specialty medications through mail order pharmacies and operates specialty care management programs that focus on improving patient compliance and adherence to drug therapy.

34. Defendant Express Scripts, Inc. ("Express Scripts"), headquartered in St. Louis, Missouri, handles millions of prescriptions each year through home delivery and retail pharmacies. Express Scripts is a Fortune 100 company with $1.2 billion in net income in 2010. It acquired CuraScript in 2004. In 2003, the company pledged to "support the use of clinically appropriate lower-cost brand name drugs."

CVS Caremark Corporation

35. Defendant CVS Caremark Corporation ("Caremark"), which is headquartered in Woonsocket, Rhode Island, and incorporated in Delaware, is the largest provider of prescription medications and the largest owner and operator of specialty pharmacies in the United States. In 2010, the company's net income exceeded $3.4 billion. Caremark fills or manages over one billion prescriptions per year.

36. At approximately 66 retail and 18 mail order "specialty pharmacy stores," Caremark provides counseling concerning, and dispenses, "specialty medications." Caremark defines "specialty medications" as ones that treat "complex conditions" and which "may be injectable and infused, high cost, [and/or] have special delivery and storage requirements." Caremark maintains on its website that patients enrolled at one of its specialty pharmacies are "assigned to a clinician-led CareTeam" that is "experienced in helping people with serious medical conditions get the most out of their health care through disease education and counseling."

37. Defendant Caremark owns Theracom, LLC, a unit that provides "commercialization support services" to the biopharmaceutical, device, diagnostic and vaccine manufacturing communities. Theracom maintains on its website that it helps pharmaceutical and other manufacturers assure successful product commercialization by, among other things, "removing barriers to access ... providing responsive, quality care to patients, and offering the highest levels of service to patients, physicians, specialty pharmacies, product distributors and other care providers." Moreover, the company bills itself as working on behalf of the manufacturer "often as an extension of the manufacturer's brand, to deliver services that will lead to successful product uptake and support the ultimate dispensing or distribution of the product on a patient-by-patient basis." Amerisource Bergen purchased the unit for $257.2 million in November 2011.

Walgreen Company

38. Defendant Walgreen Company ("Walgreen") is the nation's largest pharmacy chain, with sales of $67 billion in 2010 and more than 7,500 retail stores. Fortune magazine has ranked Walgreen as the 32nd largest company in the United States. Walgreen is headquartered

in Deerfield, Illinois, and incorporated in Illinois. Walgreen dispenses prescription medications and provides specialty pharmacy services throughout the nation.

STATUTORY BACKGROUND

39. The Federal Health Care Program Anti-Kickback Statute ("AKS"), enacted as Section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b(b), prohibits persons from paying, soliciting, or receiving illegal remunerations "in return for . . . arranging for or recommending purchasing, leasing or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1)(B) and (2)(B). The types of illegal remuneration covered specifically include kickbacks and bribes, whether paid directly or indirectly, overtly or covertly, in cash or in kind. 42 U.S.C. § 1320a-7b(b)(1) and (2). The terms "good" and "item" as used in the statute include prescription medication. Several of the states have analogous anti-kickback statutes. *See, e.g.*, Fla. Stat., Ch. 409.920(2)(e).

40. Federal regulations, codified at 42 C.F.R. 1001.952(d), identify certain narrowly defined financial transactions known as "safe harbors" that do not come within the prohibitions of the AKS. Persons or entities relying on the safe harbor exceptions to avoid liability under the AKS have the burden of affirmatively proving their strict compliance with all conditions set forth in the statutory exceptions. None of the "safe harbors" covers the violations of the Anti-Kickback Statute described in this Complaint.

41. The AKS covers any arrangement in which one purpose of the remuneration is to induce another to recommend or arrange for the purchasing, leasing or ordering of goods or items that will be paid for by a federal health program, even if other motivations are also present.

42. The HHS Office of Inspector General has identified several characteristics of arrangements among sellers, sales agents, and purchasers that appear to be associated with an increased potential for program abuse, particularly overutilization and excessive program costs. These characteristics include the following, each of which is present in the Novartis scheme at issue in this complaint:

- Compensation based on percentage of sales;
- Direct billing of a Federal health care program by the Seller for the item or services sold by the sales agent;
- Direct contact between the sales agent and physicians in a position to order items or services that are then paid for by a Federal health care program;
- Direct contact between the sales agent and Federal health care program beneficiaries;
- Use of sales agents who are health care professionals or persons in a similar position to exert undue influence on purchasers or patients; and,
- Marketing of items or services that are separately reimbursable by a Federal health care program (*e.g.*, items or services not bundled with other items or services covered by a DRG payment), whether on the basis of charges or costs.

Advisory Request No. 99-3; Advisory Request No. 98-10.

43. "[A] claim that includes items or services resulting from a violation" of the AKS "constitutes a false or fraudulent claim for purposes of [the civil False Claims Act]." 42 U.S.C. § 1320a-7b (g).

44. Compliance with the Anti-Kickback Statute is a necessary condition to the right of all health care providers, including pharmacies, to receive or retain payments from the Medicare, Medicaid, or TRICARE programs.

45. In order for a pharmacy to be eligible to bill and obtain payment from Medicaid, the state Medicaid programs require the pharmacy to abide by applicable federal and state law, including federal and/or state anti-kickback law. For example, in Illinois, in order to bill Medicaid, a pharmacy must first enter into an agreement in which it acknowledges that "compliance with such laws and handbook provisions [regarding services] is a condition of payment for all claims submitted." (Agreement for Participation in the Illinois Medical Assistance Program (available at: http://www.hfs.illinois.gov/assets/hfs1413t.pdf) (accessed on October 19, 2011).) The referenced handbook provides in turn as follows: "Providers are subject to State and federal laws pertaining to penalties for vendor fraud *and kickbacks*." (Illinois Handbook for Providers of Medical Services, Chapter 100 – General Policy & Procedures, Section 136 (available at: http://www.hfs.illinois.gov/assets/100.pdf) (accessed on October 19, 2011) (emphasis added).) In Michigan, pharmacies billing Medicaid agree to comply with the policies and procedures for the Michigan Medical Assistance Program contained in the Medicaid Provider Manual. (Michigan Medical Provider Enrollment & Trading Partner Agreement (available at: http://www.michigan.gov/documents/Dch-1625_Provider_EnrollmentAgreement1659467.pdf) (accessed on October 19, 2011).) The Michigan Provider Manual expressly states that "receiving kickbacks" is an example of prohibited "Medicaid fraud." (Michigan Department of Community Health Medicaid Provider Manual, pp. 40-41 (available at: http://www.mdch.state.mi.us/dch-medicaid/manuals/

MedicaidProviderManual.pdf) (accessed on October 19, 2011).) In Florida, pharmacies agree that they must be in compliance with federal, state and local law before Florida "may make payments for medical assistance." (Florida Non-Institutional Medicaid Provider Agreement (available at: http://www.doh.state.fl.us/demo/BrainSC/Medicaid/MPA_Non-Inst_ July_081.pdf) (accessed on October 19, 2011).) The Provider Handbook then sets forth the Florida Anti-Kickback Statute as an example of a law with which providers must comply. (Agency for Health Care Administration Florida Medicaid Provider General Handbook, Chapter 2, p. 42. (available at:https://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/HANDBOOKS/GH_09_ 090204_Provider_General_Hdbk_ver1.3.pdf) (accessed on October 19, 2011).)

46. The TRICARE program is governed by regulations set forth at 32 CFR § 199 *et seq*. Section 199.9(c) describes conduct that would be considered "fraud" against the TRICARE (formerly "CHAMPUS") program, stating in relevant part: "(12) Arrangements by providers with employees, independent contractors, suppliers, or others which appear to be designed primarily to overcharge the CHAMPUS through various means (such as commissions, fee-splitting, and kickbacks) used to divert or conceal improper or unnecessary costs or profits." The TRICARE program considers compliance with the Anti-Kickback Statute to be a condition of payment.

47. Federal law and regulations require that any health care provider who furnishes health care services that may be reimbursed under Medicare, Medicaid, or TRICARE must ensure that, to the extent of his or her authority, those services are provided "only when, and to the extent, medically necessary." 42 U.S.C.A. § 1320c-5(a); 42 C.F.R. § 1004.10. This requirement makes the health care provider the "gatekeeper" who, through the exercise of his

unbiased medical judgment, plays a critical role in determining what services will be reimbursed with federal funds. If the gatekeeper's medical judgment is corrupted – for example, by the receipt of kickbacks from a party who would benefit from the gatekeeper's decision to purchase and use that party's products in the course of patient care – then the federal health insurance system is at risk of paying for services that were not really medically necessary. The AKS was enacted to address this risk.

THE FRAUDULENT SCHEME

Overview

48. Beginning in or about January 2007 and continuing through the current time, Novartis management has employed a scheme to increase sales of certain specialty medications by corrupting the medical objectivity of pharmacists who are responsible for counseling patients on the most appropriate medication for their conditions. Novartis does so by paying Defendants Accredo, Amerisource, Bioscrip, Curascript, Caremark, Express Scripts, Medco and Walgreens ("the Specialty Pharmacy Defendants") and other specialty pharmacies valuable rewards – including patient referrals and cash payments styled as "performance rebates" or "performance discounts" -- for recommending the ordering of Novartis medications and taking other steps to increase sales of Novartis' specialty drugs. Novartis maintains scorecards of the pharmacies' performance in meeting Novartis' sales goals and pays rebates or "discounts" pegged to each pharmacy's success, if any, in increasing the quantity of sales to agreed-upon benchmark levels.

49. In a November 4, 2009, internal document entitled "Pharmacy Management Program/The Untapped Opportunity," Novartis explained that the increasingly influential role of

pharmacists in patient and physician decisions on medication means that pharmacists are in a position to drive Novartis' sales through their recommendations:

> For many patients, especially the less affluent, the pharmacist is often the first point of contact when they feel unwell. Research findings (on NSAID therapeutics) from South Africa revealed that as many as 30% of patients consult a pharmacist without having a prescription. Even if patients then go on to consult a physician, the pharmacist retains the position of "gatekeeper" by guiding patient purchases. The same research showed that 30% of patients with a prescription ask the pharmacist for a cheaper brand, and 80% of these patients accept the pharmacist's recommendation. In the end this results in 36% of patients following the pharmacist's recommendation.
>
> . . . [P]harmacists are now taking on the role of counselor and caregiver, in addition to that of dispenser. Many pharmacists even perform laboratory analysis, such as liver function tests, so that they can monitor patients' progress. The role of the pharmacist as "counselor" and "caregiver" is also supported by a study, undertaken in the US, which states that 72% of recommendations made by pharmacists to physicians on therapeutic interchanges are accepted.
>
> Pharmacists have a new role in today's competitive markets and are in a position to drive sales through recommendation/switching between the products.

50. At a November 2009 international gathering of its sales staff in Dubai, Novartis' office of Global Consumer Access and Affordability once again highlighted the critical new role of the pharmacy in Novartis' marketing efforts, and specifically advocated the use of "discount for refill" provisions in contracts with specialty pharmacies. These Novartis personnel noted that "traditional business models" involving marketing Novartis products to doctors were no longer as successful due, in part, to regulations designed to safeguard patients and taxpayer dollars.

On a PowerPoint document, they then highlighted several ways in which Novartis can "leverage the influence of the pharmacy" to increase Novartis product sales, including:

> Reminders & Discounts: provide patients on chronic therapy with reminders and services from pharmacies to maintain compliance; offer discounts to drive refills.

51. In its PowerPoint, Novartis observed that the potential effectiveness of using "pricing/discounting to incentivize adherence" was "high." Similarly, Novartis stated that the potential effectiveness of an "intervention program" to "leverage pharmacy to remind patients or reinforce the importance of adherence" was "high." Novartis personnel use the term "adherence" to mean "refills" -- even though increasing refills does not mean that patients will take the refilled medication on schedule and, as a result, "adhere" to the prescribed regimen.

52. Novartis' Head of U.S. Management Markets and Mature Products, Don DeGolyer, has trained Novartis sales representatives on the fact that the pharmacists Novartis seeks to influence have certain "unmet needs," including, in particular, specialty pharmacies "looking for pharmaco [pharmaceutical company] reimbursement for services (*e.g.*, compliance programs.)" In using the phrase "compliance programs" in this context, DeGolyer was not referring to a compliance program designed to ensure adherence to applicable law. Rather, he was using the phrase to refer to a "medication compliance program," a term that Novartis defines in training materials for its sales force as "the extent to which a patient acts in accordance with the prescribed interval, and the dose of a dosing regimen." In practice, Novartis personnel use the phrase "compliance programs" along with the phrase "adherence programs" to reference programs in which specialty pharmacies use clinical staff and sales personnel to drive up the

sales of Novartis products, by, among other things, contacting customers to encourage them to order Novartis' specialty medications.

53. The first aspect of Novartis' specialty pharmacy scheme involves Novartis channeling a new patient -- *i.e.*, a patient who has been prescribed the Novartis specialty medication for the first time -- to Novartis web sites or call centers, or to so-called "Novartis reimbursement hubs," for guidance with insurance reimbursement and information on where and how to fill their prescription.

54. Novartis' designated call centers and web sites, managed by Novartis employees, steer patients to specialty pharmacies to fill their prescriptions for specialty medications.

55. The reimbursement hubs are run on behalf of Novartis by outside entities, such as Defendant Caremark's subsidiary, Theracom, LLC, and Defendant Amerisource's "LASH" consulting services group, that specialize in improving patient access to medications and increasing product sales. Pursuant to their contracts with Novartis, these hubs not only provide insurance advice to patients and doctors, but also direct patients to fill their prescription at one of a select group of specialty pharmacies that are part of the "Novartis specialty pharmacy network."

56. As set forth in greater detail below, unbeknownst to the patients ordering Novartis medications, the specialty pharmacies to which they are directed by Novartis web sites, call centers and reimbursement hubs are pharmacies that are paid by Novartis for their success in shifting market share from the competitors' products to the Novartis product by getting new patients onto the Novartis product and maximizing the number of orders and doses of the Novartis product per existing patient.

57. The second aspect of the scheme involves Novartis' selection of a limited number of specialty pharmacies for possible inclusion in its specialty pharmacy network. To be considered for inclusion, the specialty pharmacy must demonstrate that it will use effective techniques to maximize the quantity of the drug dispensed, including calling patients to encourage them to order or re-order the Novartis medication. It must be willing to agree: (a) to continue using these techniques; (b) to be benchmarked against its peers through a scorecard reflecting pharmacy achievement of performance metrics relating to drug sales, such as market share and quantity of drug dispensed per patient; and (c) to send Novartis' reimbursement hub the names of patients who are not refilling their orders of the Novartis drug at issue.

58. The aspect of the scheme involves Novartis' Specialty Pharmacy Team entering into contracts with those pharmacies that have been selected to be part of the network. These contracts include financial incentives for increasing market share and/or increasing total quantities of the drug sold per patient, provisions requiring the pharmacies to submit detailed data on sales to Novartis so they can be assessed vis-à-vis the other specialty pharmacies in Novartis' distribution network on monthly "scorecards" and other provisions that incentivize the pharmacies to increase patient orders of the Novartis product. These contracts have been negotiated by four Novartis Associate Directors for Specialty Pharmacy and by Novartis employees within the Oncology business unit. These Associate Directors are in a reporting chain that includes Novartis' Vice-President for Managed Markets & Market Access, United States.

59. Novartis' contracts with specialty pharmacies typically offer base-level payments characterized as discounts or rebates in the range of one to three percent of Novartis' sales prices. The pharmacies earn what is known within Novartis as a "first category rebate" or

"adherence support" by undertaking to call patients to educate them about the Novartis product and the underlying disease that it treats, to provide advice on the drug's side effects and to encourage patients to remain on the Novartis product.

60. Pursuant to many of Novartis' contracts with specialty pharmacies, the pharmacy can also earn what is known within Novartis as a "second category rebate" by achieving performance metrics specified in the contract. These second category rebates, which are sometimes characterized as "performance discounts," are paid based on the quantity of the Novartis drug dispensed or the increased market share obtained for the Novartis product; they are not paid merely because of the pharmacy's purchase of the product. As such, they are performance-based payments rather than classic volume rebates. In other words, Novartis conditions its continued payment of performance-based discounts or rebates to specialty pharmacies on the extent to which the pharmacists are successful in convincing patients and their physicians to order and reorder Novartis medication and in pushing up the total quantity of Novartis medication dispensed.

61. To supplement the contractual, financial incentives, Novartis also uses the reimbursement hubs' control over patient referrals to the specialty pharmacies in Novartis' distribution network to incentivize the specialty pharmacies to increase the sales of Novartis medications. Thus, when the patient's health insurer has not designated a specific pharmacy, Novartis, through its control of the reimbursement hub, has control over the referral of patients to the various specialty pharmacies in its distribution network. Novartis sometimes will direct the reimbursement hub to channel such "undesignated patients" on an evenly rotating basis. When some pharmacies are doing better than others at increasing the sales of the Novartis specialty

medication, however, Novartis sometimes will direct the hub to reward the better performing pharmacies, and penalize the lagging pharmacies, by sending more patients to the higher performing pharmacies than to the others.

62. The specialty pharmacies subject to these kickback arrangements have agreed with Novartis to engage in a number of coordinated initiatives to achieve Novartis' goals regarding market share and the quantity of drug to be dispensed per patient.

63. The pharmacies' market-share-focused initiatives have included a number of proactive efforts by the pharmacies to get new patients onto the Novartis drug, such as initiatives: to "ensure ALL appropriate patients" are on Novartis' immunosuppressive drug Myfortic; to get patients to switch off Novartis' oncology drug Gleevec sooner than they would otherwise and placed on Novartis' second-line oncology drug Tasigna rather than on one of the competing, second-line treatments; to dispense Novartis' cystic fibrosis drug TOBI instead of the less expensive, compounded tobramycin product; and, to "convert" patients from betaseron to the Novartis drug Extavia, and from Arcalyst to the Novartis drug IIaris CAPs.

64. To increase the amount of drug dispensed per patient, the pharmacies have launched initiatives to use nurses with perceived professional competence and objectivity, as well as other pharmacy staff perceived by patients to be acting on behalf of the pharmacy's professional staff, to "intervene" with patients and recommend that patients reorder the Novartis product. These programs have included "High Touch Specialty Care" programs launched to increase sales of Novartis' oncology products Exjade, Gleevec and Tasigna. The Novartis reimbursement hubs run by third parties also pressure patients to refill or request additional prescriptions of Novartis products by having their own telemarketers place calls to patients

urging them to do so and by notifying physicians when patients decline to do so. In addition, to further increase the amount of Novartis product dispensed per patient, the pharmacies have undertaken coordinated campaigns to recommend that patients increase their dosing of Novartis products to the highest approved dose. Pharmacies have undertaken such dosing initiatives with regard to Gleevec and Exjade, for example.

65. Novartis sometimes requests that pharmacy companies that have both retail and specialty pharmacies channel their customers who are on Novartis specialty drugs from their retail to their specialty pharmacies. Novartis does this because specialty pharmacies interact more often with patients and consequently are better positioned to intervene with patients and recommend Novartis products. Novartis sometimes employs this tactic when it wishes the specialty pharmacies to help switch patients from one Novartis product to another Novartis product that treats the same condition. There are a number of reasons why it is sometimes in Novartis' financial interest to switch patients from one Novartis product to another. For example, the first Novartis product may be going off patent or have less of a competitive advantage than a second, newer Novartis product. In addition, sometimes patients become resistant to or intolerant of a Novartis drug and have to switch to another treatment for medical reasons; Novartis would prefer that the patient switch to an alternative Novartis product than to a competitor's product. Novartis uses specialty pharmacies to intervene with patients in each of these circumstances to maximize the changes that they will switch over to a second Novartis product.

66. Novartis' contracts with specialty pharmacies provide for preparation of monthly scorecards evaluating the success of the specialty pharmacy in achieving the performance

metrics, which Novartis compares against the scorecards of the pharmacy's competitors. The pharmacies know they are being compared with their competitors. They are aware that they may lose the right to participate in Novartis' specialty pharmacy network, and to receive lucrative patient referrals and compensation, if they fall short on order numbers compared to their competitors. Removal from the Novartis specialty pharmacy network not only means deprivation of the lucrative rebate opportunities that Novartis offers to pharmacies in the network, but also, and perhaps even more importantly, means that Novartis' reimbursement hub will no longer be directing any patients to the pharmacy.

67. Novartis personnel use the term "adherence" or "compliance" to describe the results of "high touch" specialty pharmacy programs that involve: i) calls by pharmacists, nurses and other pharmacy staff to patients urging them to order the Novartis product; and, ii) other steps to increase the sales of Novartis products. In reality, however, Novartis's contracting efforts are focused on increasing the quantities of the drug dispensed regardless of whether that leads to greater patient "compliance" with or "adherence" to a drug regimen. While Novartis, the pharmacies and the health plans track the quantity of medication dispensed to given patients, they do not track whether the patients actually take the medication dispensed to them. A greater amount of medication dispensed to a patient does not necessarily translate into greater patient adherence to or compliance with a prescription medication regimen. Often, and especially when little or no co-payment is required from the patient, a patient will order medication simply because he is asked to do so and not because he intends to continue on the medication. Consequently, Novartis personnel internally refer to the "adherence" aspect of the specialty pharmacy program by its true function, *i.e.*, as a "refill program."

68. The Novartis performance-based contracts corrupt the disinterested, objective clinical advice that otherwise would be provided by specialty pharmacies to patients. There are many different medications made by different companies that are available to treat the illnesses treated by Novartis medications. Some are safer or more effective than others, depending on the patient's unique health profile. Some are less expensive for the payer; also, if there is any co-pay, "donut hole" or deductible involved, some are less expensive for the patient. Moreover, in some cases, the best medical approach may not require taking prescription medication. Patients may wish to discontinue a Novartis medication because of the drug's serious side effects, or because the drug is not working as expected. They want objective advice from their pharmacist about whether they should consider a different medication or medical approach. In counseling a patient on whether to fill a Novartis medication, a pharmacist or his or her employee is supposed to listen objectively to the patient's description of his or her health condition, including any side effects that might be arising from the medication, and then provide objective advice on whether to stay on the Novartis drug or consider switching over to a different medication or another medical approach. When the pharmacy is being compensated for its success in meeting the manufacturer's dispensing goals, however, that objectivity goes out the window. Rather than providing disinterested clinical advice, the pharmacy provides advice driven by its own financial considerations.

69. As set forth more fully below, Novartis induces pharmacists to recommend Novartis specialty medications that often are more expensive for payers, and/or less efficacious and safe for patients.

70. Novartis does not disclose to health plans, patients or physicians that it pays financial incentives to the specialty pharmacies based on the pharmacies' performance in driving up sales of Novartis' products. Nor do the specialty pharmacies disclose to patients that Novartis pays them based on their success in increasing the quantity of drugs dispensed. Accordingly, the health plans, patients and doctors incorrectly assume that the pharmacies, when calling patients about their medication needs, are complying with their legal and professional obligations to provide objective clinical advice. The patients and physicians rely on this incorrect assumption in deciding whether to adopt the pharmacy's recommendations concerning the appropriate medication for the patient.

71. More often than not, physicians will follow the recommendation of a pharmacist concerning the best medication for a patient. As Novartis has informed its sales and marketing personnel, a recent study shows that physicians adopt the recommendations of community pharmacists more than 70% of the time.

72. Defendant Novartis has employed the foregoing scheme for the following specialty medications, among others: Gleevec, Exjade, Tasigna, TOBI, and Myfortic. The specialty pharmacies that are part of Novartis' network, such as the Specialty Pharmacy Defendants, submit claims for these medications to publicly-funded health care programs, including claims for refill orders obtained as a result of Novartis' violation of the AKS.

73. The Specialty Pharmacy Defendants and the other specialty pharmacies that are part of Novartis' distribution networks for Gleevec, Exjade, Tasigna, TOBI, and Myfortic, as well as other specialty medications, have signed Medicaid provider agreements in the states in which they do business. These agreements require compliance with all federal and state laws,

regulations and program guidance applicable to the Medicaid program, which include, *inter alia*, the AKS. These pharmacies have been required to sign the provider agreements as a condition of billing and receiving payment from Medicaid. In signing these agreements, these specialty pharmacies knowingly have falsely represented such compliance.

Gleevec, Exjade, & Tasigna

74. Since approximately 2007, Novartis also has used the scheme to market Exjade, an iron-chelating medication approved by the FDA in 2005 that is used to remove excessive amounts of iron from the blood. Exjade is prescribed for patients with an underlying illness, such as Sickle Cell Disease or Thalassemia, which often leads to excessive levels of blood iron. Since approximately 2007**,** Novartis also has employed the scheme set forth above to market Gleevec, a medication for leukemia and other blood cancers approved by the FDA in 2001. Since approximately 2008**,** Novartis has used the scheme for Tasigna, a salvage drug that the FDA approved for the treatment of leukemia in October 2007. Tasigna is often prescribed as a "second line treatment" for leukemia patients who do not do well on Gleevec, either because of intolerable side effects or because the drug stops working for them

75. Gleevec, Exjade, and Tasigna are "blockbuster" oncology medications. In 2010 alone, Novartis' net sales of Gleevec, Exjade and Tasigna exceeded $1.284 billion, $263 million and $133 million, respectively. Novartis documents indicate that approximately 40% of Exjade sales are reimbursed by Medicaid, Medicare or other government health programs. Relator understands that the percentage of sales reimbursed by public health programs is comparable for Gleevec and Tasigna.

76. Gleevec, Exjade and Tasigna are expensive medications. In the first quarter of 2011, Florida Medicaid data indicates that the average reimbursement per claim was $5,144 for Gleevec 400 mg., $5,378 for Exjade 500 mg., and $7,664 for Tasigna 150 mg.

77. The FDA-required product insert for Gleevec warns clinicians of the following complications that can arise from Gleevec: Dermatologic Toxicities, Fluid Retention and Edema, Gastrointestinal Disorders, Hemorrhage, Hematologic Toxicity, Hepatotoxicity, and Hepatic Impairment. The label also warns of the possibility of "Toxicities from Long-Term Use."

78. Tasigna's label includes a "black box warning" cautioning physicians and patients that the drug poses cardiovascular risks, including the risk of death, because the drug can prolong a phase of the heart's electrical cycle called the "QT interval." Tasigna is significantly less safe than its main competitor, the Bristol-Myers Squibb medication Sprycel (dasatinib), which, like Tasigna, is approved as a second-line treatment for chronic myelogenous leukemia. While Tasigna has a black box warning on its label, Sprycel does not. Moreover, a thirty-day supply of Tasigna 150 mg. is no less expensive than a thirty-day supply of Sprycel; indeed, in at least some states, Tasigna is marginally more expensive for Medicaid. Thus, a thirty-day supply of Tasigna 150 mg currently costs Florida Medicaid $8,181, while a thirty-day supply of Sprycel 100 mg. currently costs Florida Medicaid $7,882.

79. Exjade's label includes a black box warning advising doctors and patients that the drug can cause renal or hepatic failure or gastrointestinal hemorrhage. Exjade is a non-preferred medication on the formularies of some health care programs, including, for example, California Medicaid and Florida Medicaid.

80. Novartis uses the term "EPASS," an acronym for the term "Exjade Patient Assistance and Support System," to describe its distribution network for Exjade, a system composed of a reimbursement hub operated by the LASH Group and three specialty pharmacies: US Bioservices, Bioscrip and Accredo. In a first quarter 2008 update for the Oncology National sales team**,** Novartis employee Paul Pochtar, Vice President for Oncology Managed Markets, listed the oncology division's innovative actions to "[l]everage Specialty Pharmacy capabilities." These actions included the addition of a "performance component to EPASS pharmacies to achieve adherence targets" for Exjade. The update characterized "adherence" as one of the four "core pillars" to drive sales of Exjade," The update also identified "New Patient Starts" and "Dose" as issues and opportunities for Exjade, and identified "Specialty Pharmacy" as a "Key Tactic/Action" to drive "Competitive Position" and "Dose Optimization."

81. The first quarter 2008 update for the Oncology National sales team also discussed implementation of a "Big3 Specialty Pharmacy Initiative" for Gleevec and Tasigna that would "transition Retail to Specialty" and "[e]nhance patient care & adherence." It referenced as "innovative actions" efforts to "Strengthen Alignment with Franchises" through "Good integration of Customer Marketing in working with Business Franchise structure, such as "Exjade, Gleevec/ Tasigna, Sandostatin LAR - Specialty Pharmacy initiatives." (Within Novartis' organizational structure, the term "franchise" refers to a Novartis business unit focused on a specific therapeutic area.) "Dose Optimization" was specifically identified as an issue and opportunity for Gleevec.

82. In an April 2008 webcast, Novartis management informed employees that it also would utilize specialty pharmacies as a "key tactic" to "push for an early switch" from Gleevec.

Novartis aimed to achieve a "preferred 2nd line position" for Tasigna by getting patients who were not responding well to Gleevec to switch off Gleevec earlier than they would otherwise and then start on Tasigna rather than Sprycel or another second-line treatment.

83. In March 2009, Richard Andes, Novartis Director of Multiple Sclerosis Brand Managed Markets, presented training to the Novartis sales force. In the training, he noted the resounding success of Novartis' specialty pharmacy model in the oncology area. His PowerPoint slides illustrated this through a table showing Gleevec's "adherence" (*i.e.*, refill) rates at both specialty and retail/mail pharmacies. For the Defendant Accredo/Medco, refill rates were 58% at retail/mail pharmacies, and 78% at specialty pharmacies. For Defendant Caremark, refill rates were 63% at retail/mail pharmacies, and 92% at specialty pharmacies. For the Defendant Curascript/ESI, they were 53% at retail/mail pharmacies, and 65% at specialty pharmacies.

84. As of September 14, 2009, Novartis had entered into contracts with the following specialty pharmacies to compensate the pharmacies for increasing sales of Gleevec and Tasigna as part of the "Specialty Pharmacy Initiative": Defendant Accredo/Medco, Defendant Caremark, and Defendant ESI/Curascript. According to Novartis, the specialty pharmacies were making "[p]ro-active outbound calls to physicians prescribing > 300mg" of Gleevec, and adherence to Gleevec of patients treated by specialty pharmacies was higher than the patients treated by retail pharmacies. Moreover, 8,000 patients of the specialty pharmacies dispensing Gleevec and Tasigna were receiving "high touch specialty care"—an increase from the 5,000 patients in January 2008.

85. As of September 14, 2009, Defendants Accredo, defendant BioScrip, and defendant Amerisource's USBioservices were part of the EPASS Network that dispensed

Exjade. As of September 14, 2009, these specialty pharmacies were subject to "Performance Driven" referral of patients with new prescriptions, *i.e.*, Novartis was directing its reimbursement hub, when referring new patients, to discriminate in favor of the pharmacy that had achieved the greatest success in meeting Novartis' sales goals. Moreover, by this date, 7,000 of these pharmacies' customers were receiving "high touch specialty care." As a result, according to Novartis, there had been a "[s]ignificant improvement" in these pharmacies' "performance."

86. In a September 14, 2009 Novartis presentation titled "U.S. Oncology Town Hall – Field Web Cast," Novartis identified as key priorities, among others: "Dose Optimization" for Gleevec; "Seize 2nd line leadership" for Tasigna; and "New patient starts," "Treat at 1000," "Dose," and "Adherence" for Exjade.

87. Novartis directs physicians and patients to contact a reimbursement hub called "E-PASS Administrator" for assistance with regard to Exjade prescriptions and reimbursement. According to PowerPoint slides presented in or about the fall of 2007 by Novartis managers Emily Chee (Director, Brand Managed Markets, Hematology Business Franchise) and Bill Conkling (Regional Business Director East, Oncology Business Franchise) the reimbursement hub E-PASS "refers [each] case to appropriate specialty pharmacy or PAP." E-PASS Administrator is operated by the LASH Group, which is part of Defendant Amerisource Bergen's Consulting Services division.

88. Beginning in approximately 2009, patients have been directed to contact the Novartis-managed programs MyCMLCircle or MyGISTcircle for assistance with regard to Gleevec and Tasigna prescriptions. In addition, prior to September 2010, patients were

instructed to contact the Novartis websites www.cmlalliance.com and www.gistalliance.com for assistance with such prescriptions.

89. According to the Chee/Conkling PowerPoint presentation, a specialty pharmacy in the Novartis network for Exjade "calls patient monthly for refill and monitors compliance." To incentivize the pharmacy to make calls that increase the total Exjade refill orders, Novartis enters into a contract with the pharmacy that provides rebates based on the pharmacy's achievement of agreed-upon "performance metrics" relating to Exjade refills. The rebates are "[p]aid as fixed $ amt per shipment – approx $50 per shipment." Novartis and the pharmacy then conduct "[m]onthly discussions on report card performance." The PowerPoint notes that: "Monthly adherence scorecards allow Novartis and pharmacies to carefully monitor adherence." The Chee/Conkling presentation also states that nurses at one specialty pharmacy "have been able to address one of the key reasons for discontinuation – side effects" and that nurses have had a "significant impact on Exjade adherence." As evidence, the presentation points out that there had been a $1.4 million increase in Exjade sales and 17% increase in the number of shipments received by patients in first six months of therapy (the presentation equates shipments *received* to "better outcomes for patients"). The presentation further notes that two other specialty pharmacies were "implementing Nurse programs and increasing patient contact in the early months of therapy." Patients, the presentation explained, were "more willing to open up to a nurse than a pharmacist." In 2008, Chee and Conkling were nominated for a Novartis Global Nexus Award for their "new, innovative, and breakthrough thinking" with regard to the Specialty Pharmacy High Touch Model they developed to market Exjade. The presentation identified BioScrip as the first specialty pharmacy to implement the High Touch Model. In connection

with this nomination, Novartis management praised Chee and Conkling for the following aspects of the program for Exjade:

- Development of the patient adherence scorecards was an internal crossfunctional team effort involving Marketing, Market Research, Business Analysis and Customer Marketing.

- To provide a further incentive to our pharmacy partners in 2008, an incentive program ($320,000) will reward the pharmacies for hitting adherence targets.

Tobramycin Inhalation Solution ("TOBI")

90. In light of the success of the "specialty pharmacy" model in which Novartis pays financial rewards to pharmacies that increase sales of Novartis special oncology products through high touch specialty care programs that recommend use of Novartis products, in approximately 2007, Novartis decided to export the model to other specialty products outside the area of oncology. Since approximately 2008, Novartis has used financial incentives in contracts with specialty pharmacies, including the defendant pharmacy chains and networks, to compensate pharmacies for increasing patient orders of Tobramycin Inhalation Solution (TOBI), an inhaled antibiotic for cystic fibrosis patients.

91. TOBI, which has been the medication marketed by Relator, was approved by the FDA on November 27, 1997. In 2010, Novartis' gross sales of the drug exceeded $ 280 million, with its net sales exceeding $196 million. Approximately 35% of TOBI sales are paid for by public health programs. Medicaid reimburses approximately 31.1% of the public health program sales, with Medicare Part B and Part D covering the remaining 68.9%.

92. Like the oncology medications discussed above, TOBI is a very expensive drug. In Florida, Medicaid paid an average of $4,195 per claim for TOBI in the first quarter of 2011.

93. TOBI's package insert warns clinicians that TOBI can cause dangerous side effects, including Ototoxicity, Nephrotoxicity, Muscular Disorders, and Bronchospasm. The product label advises clinicians to monitor patients for these adverse reactions.

94. Novartis' brand product TOBI is significantly more expensive for payers than compounded generic tobramycin and other compounded generic products, which are also generally covered by Medicaid. There is no evidence that TOBI is more efficacious or safe than compounded generic tobramycin or the other compounded generic alternatives when prepared by a competent specialty pharmacy. Consequently, in many cases there may not be a legitimate justification for a specialty pharmacy to recommend TOBI over a compounded generic product.

95. In 2007, in internal business plans, Novartis contract managers first proposed paying specialty pharmacies who achieved certain performance metrics on a per patient/per dispense basis "similar to the Gleevec initiative" to operate a high touch program involving pharmacy outreach to patients encouraging refills. The Novartis contract managers proposed characterizing this kind of payment "as a rebate to ensure consistently [sic] throughout Novartis." Novartis contract personnel observed that patient "compliance rates," *i.e.*, refill rates, were significantly higher when specialty pharmacies were used by patients. For example, at Caremark, only 70% of customers using retail or mail order pharmacies refilled their medication, while 88% of customers using specialty pharmacies did so.

96. Novartis' 2007 internal business plans for the marketing of TOBI contemplated a "per patient/per dispense" payment to specialty pharmacies of $34, $69, or $103, depending upon the pharmacy's ability to meet the performance metrics relating to "compliance," *i.e.*, prescription refill rates. The business plans indicated that the specialty pharmacies first would

receive a "category 1 rebate" to allow them to "initiate programs supporting TOBI." These programs, also referred to within Novartis as "service initiatives," would require specialty pharmacies to "manage their 'own' TOBI patients to drive compliance, provide insights into care, and secure data insights." In other words, Novartis would pay the pharmacies in exchange for their undertaking regularly to contact patients encouraging them to fill existing TOBI prescriptions, inquiring about their health care, and transmitting the patients' health care information to Defendant Caremark's Theracom unit and Novartis. The pharmacies also would receive a "category 2 rebate" as reimbursement for achieving "higher compliance," the misnomer used within the Novartis contracting organization to describe higher ordering rates. Pursuant to a contract with Novartis, Caremark's Theracom unit would operate a reimbursement hub for TOBI called "TOBICARE." TOBICARE would steer patients to the specialty pharmacies in the Novartis network.

97. As of April 2010, Novartis documents indicate that a forthcoming "Specialty Pharmacy (SPP) Network" for TOBI would include defendant Accredo, Aetna, A-Med, Armada, defendant Caremark, CF Services, Cigna, defendant Curascript, Precision Rx, Rx Solutions, and defendant Walgreens SPP. These documents also stated that an objective of TOBICARE was to "Increase TOBI refills through the Specialty Pharmacy."

98. On July 15, 2010, Mark Smith, Novartis Senior Director for U.S. Managed Markets, claimed in a discussion with Relator that Novartis' performance incentives for specialty pharmacies were legal under a safe harbor to the AKS because of high unmet medical needs of TOBI patients. There is no such safe harbor.

99. In a September 1, 2010, PowerPoint presentation, Novartis' Contract Operations Team for TOBI reported that they were negotiating a contract with Foundation Care that would provide a "performance rebate" on TOBI purchases based on "volume and market share requirements" along with "patient adherence support." "Patient adherence support" refers to a Novartis payment to a specialty pharmacy made in exchange for the pharmacy employing staff to encourage customers to refill their TOBI prescriptions, and, if they decline to do so, alerting the TOBICARE reimbursement hub run by Caremark's Theracom unit so that TOBICARE can follow-up with the person's physician. The stated contracting objectives were to "[g]row TOBI volume and market share" and "[i]mprove patient adherence by leveraging Foundation Care's Intervention Programs and Capabilities." As Novartis believed that Foundation Care advocated for a competitor drug, i.e., compounded tobramycin, the presentation stated that the goal was to "discourage this account from promoting and advocating compounded tobramycin."

100. At a meeting in San Diego, California, between March 21 and 24, 2011, Novartis' Associate Director for Marketing, Kiery Jackson, admitted during a group discussion that the TOBICARE program is not really an adherence program, but rather is more of a "refill program." Present at the meeting were Chris Lyon and David Kester, both of whom pointed out that Novartis' customers would not like to hear this. In using the term "customers" in this setting, Lyon and Kester were referring to physicians and other health care providers.

101. On April 8, 2011, Novartis had active contracts with six owners of specialty pharmacies pursuant to which Novartis paid the pharmacies to increase TOBI refill numbers, using "category 1" rebates to launch a pharmacy's service initiative, and "category 2" rebates to reward pharmacies that achieved certain performance goals in terms of the number of TOBI

refills ordered by patients. According to Max Stillwell, a Novartis Transplant Regional Account Manager, the six were Defendant Accredo, Defendant Caremark, Cigna Tel-Drug, Defendant Curascript/ESI, A-Med, and CF Services. Stillwell explained that the specialty pharmacies contact the patient seven to ten days before their refill would be due and ask the patient if the specialty pharmacy can ship another refill. In addition, since approximately April 2010, TOBICARE has directed patients to specialized pharmacies rather than retail pharmacies so they will receive these follow-up calls requesting refill orders. TOBICARE also calls the patient to encourage refills, usually placing their calls six weeks before the next refill is due. According to Stillwell, specialty pharmacies only receive the rebate if they actually dispense TOBI. The pharmacy's mere purchase of the drug from Novartis does not entitle them to a rebate unless that purchase leads to a refill, *i.e.*, an order for the drug. Many of these refill orders are reimbursed by public health programs.

102. On an April 28, 2011 call concerning TOBICARE, Oscar Urcia from Novartis' customer service department confirmed that the six specialty pharmacies mentioned in the preceding paragraph are "approved TOBICARE specialty pharmacies." Novartis used the term "approved specialty pharmacies" to refer to pharmacies with which Novartis has entered into contracts providing incentive rebates as a reward for increased refill numbers. Urcia stated on the call that TOBICARE employs three customer service agents that handle 50 to 75 calls per day, including calls in which they contact patients to check for insurance changes, check for any side effects or other issues relating to the patient's use of TOBI, and ask if the patients are ready for the next refill. If the patient does not want a refill, TOBICARE notifies the physician that the patient is off therapy.

103. On May 19, 2011, Steve Davis ("Davis"), Assistant Director of Novartis' Specialty Pharmacy Group – the group that negotiates contracts between Novartis and specialty pharmacies – spoke by telephone with Relator and other Novartis employees. During the call, Davis said that, since approximately 2008, Novartis has used the specialty pharmacy model for TOBI because the "high touch" approach of specialty pharmacies, which include calls by sales staff to customers concerning prescription refills, increases the percentage of prescriptions that ultimately are refilled by patients (and largely paid for by the taxpayer). At retail pharmacies, the average number of TOBI prescription fills is 2.1 per patient per year; at specialty pharmacies, the average number of TOBI prescription fills is 4.1 per patient per year out of a maximum of 6.5 per year. (TOBI is taken twice a day every other month.)

104. Davis explained that Novartis uses two separate methods to maximize the number of patients who receive calls from specialty pharmacy staff encouraging refills. First, Novartis and Defendant Caremark drive patients towards specialty pharmacies for their prescription needs by asking patients and doctors to contact TOBICARE (the reimbursement hub run by Defendant Caremark's subsidiary, Theracom) for all questions on payer reimbursement for TOBI. Theracom in turn has been instructed to direct inquiring patients and doctors' offices to specialty pharmacies in the first instance. Second, Novartis offers special rebates to specialty pharmacies that adopt such a "high touch" approach; the rebates are directly correlated with the average number of TOBI refills achieved by the pharmacy per year. According to Davis, Novartis only pays the specialty pharmacies these rebates if the refills were actually shipped from a Specialty Pharmacy location. This places pressure on the pharmacy chains to channel retail patients into their specialty pharmacies where they will be solicited for refills.

105. According to additional comments made by Davis on the May 19th call, Novartis at that time was finalizing a contract with Foundation Care that similarly would provide the company's specialty pharmacies with a tiered rebate structure tied to "performance metrics" to "encourage growth of TOBI market share." Davis explained that, while Novartis is willing to negotiate such rebate provisions with Caremark's specialty pharmacies, it is not willing to do so with Caremark's regular retail stores.

106. The combination of Theracom's efforts to steer patients towards "high touch" specialty pharmacies, and the performance-based rebates that Novartis offers only to "high touch" specialty pharmacies, has led to a dramatic increase in the percentage of TOBI sales made by these specialized pharmacies. Davis noted on the May 19th call that the percentage of TOBI sales generated by specialty pharmacies increased from 11% of the total TOBI sales in 2007, to approximately 35% of the total TOBI sales in 2010.

107. As of August 1, 2011, Novartis had active contracts with at least seven owners of specialty pharmacies pursuant to which Novartis paid the pharmacies to increase TOBI refill numbers using category 1 rebates to launch a pharmacy's service initiative and category 2 rebates to reward pharmacies that achieved certain performance goals in terms of the number of TOBI refills ordered by patients. According to Rob Rindini, Novartis Associate Director for Specialty Pharmacy, as of August 2011, the "TOBI SPs" include CIGNA Home Delivery, Defendant Caremark, Defendant Curascript, Defendant Accredo, A-Med, CF Services and Defendant Walgreens Specialty Pharmacy.

Myfortic

108. Novartis has also implemented a specialty pharmacy kickback scheme to increase the company's sales of Myfortic, an immunosuppressant prescribed following organ transplant. The FDA approved Myfortic in November 1997. In 2010, Novartis earned approximately $163 million from sales of this drug.

109. Myfortic is generally more expensive than the generic versions of its competitor, Cellcept (mycophenalate motefil), which gives Myfortic an immediate competitive disadvantage.

110. Like other immunosuppressants, Myfortic's product label contains a black box warning advising patients and physicians that the drug "may lead to increased susceptibility to infection and possible development of lymphomas and other neoplasms." The black box warning underscores the importance of particularly careful physician supervision of patient use of the drug, with all pertinent information on patient health transmitted to the physician: "Only physicians experienced in immunosuppressive therapy and management of organ transplant recipients should use Myfortic . . . Patients receiving myfortic should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient." (Emphasis in original.)

111. To market Myfortic, Novartis must overcome the handicap of the product's relatively higher cost compared to the generic competition. To expand sales of the drug notwithstanding this price disadvantage, Novartis management, in an August 5, 2011, presentation entitled "XLR8: the myfortic® Acceleration Plan," announced the company's arrangements to: "Partner with SPs [specialty pharmacies] to ensure ALL appropriate patients

are on myfortic." In other words, Novartis was entering into financial arrangements with specialty pharmacies to induce them to take proactive steps to move transplant patients onto Myfortic. Management disclosed the "[n]ew specialty pharmacy contracts designed to drive myfortic® net sales growth" with "risk mitigated: rebates paid only when performance hurdles achieved." Management clarified that the rebates would increase incrementally according to the specialty pharmacy's performance level. The document also stated that the specialty pharmacies with which Novartis had contracted in 2011 included defendant Walgreens, OptumRx, TwentyTen, Transcript, Kings, and Kilgore.

112. In an August 22, 2011, email from Jim Niebanck, Director of Franchise Operations, Transplants, Relator was told that "[for] the SPs [specialty pharmacies] that we [Novartis] contract with, their performance rebates are based on their myfortic market share compared to the national market share."

113. Novartis' use of financial incentives to increase the market share of Myfortic compared to the competition directly affects the quality of patient care. The sales personnel that the specialty pharmacies employ to counsel patients to order Myfortic -- people with the equivalent of a high school diploma, and no professional training or licensing -- are unqualified to provide any medical advice to customers considering whether to order Myfortic. Moreover, unknown to the patient, any advice they provide is also biased by the financial incentives paid by Novartis. In the case of a drug with a black box warning, the potential consequences are particularly severe for a patient who might take the drug based on the urging of pharmacy sales staff, rather than on advice rendered by an objective health care practitioner skilled in immunosuppressive therapy and cognizant of the patient's full health profile.

DAMAGES

114. Through the foregoing conduct, Defendant Novartis knowingly has caused specialty pharmacies to submit false claims to Medicaid, Medicare and other federal health care programs. Through the foregoing conduct, Defendants Caremark and Amerisource knowingly have caused the submission of false claims to Medicaid, Medicare and other federal health care programs. Through the foregoing conduct, the Specialty Pharmacy Defendants all have knowingly submitted false claims to Medicaid, Medicare and other federal and state health care programs. The claims are false because they seek payment for orders of prescription medication that resulted from violations of the AKS. The United States and the state Plaintiffs have been damaged by the amounts they have paid to reimburse specialty pharmacies in the Novartis network for orders of Gleevec, Exjade, Tasigna, TOBI, Myfortic, and other specialty medications marketed through the scheme set forth herein.

COUNT I

(Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*)

115. This is a civil action by Plaintiff David M. Kester, acting on behalf of and in the name of the United States, against the Defendants under the False Claims Act.

116. Plaintiff realleges and incorporates by reference paragraphs 1 through 114 as though fully set forth herein.

117. The Defendants knowingly have presented or have caused to be presented false or fraudulent claims for payment by the United States, in violation of 31 U.S.C. § 3729(a)(1)(A) (post-May 2009 amendment) and 31 U.S.C. § 3729(a)(1) (pre-May 2009 amendment).

118. The Defendants knowingly have made or used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the United States, in violation of 31 U.S.C. § 3729(a)(1)(B) (post-May 2009 amendment) and 31 U.S.C. § 3729(a)(2) (pre-May 2009 amendment).

119. Defendants have conspired with each other, as well as others, to defraud the Government by getting false or fraudulent claims allowed or paid, in violation of 31 U.S.C. § 3729(a)(1)(C) (post-May 2009 amendments) and 31 U.S.C. § 3729(a)(3) (pre-May 2009 amendment).

120. The Defendant specialty pharmacies have knowingly and improperly avoided obligations to pay or transmit money to the Government, in violation of 31 U.S.C. § 3729 (a)(1)(G) (2009).

121. Because of the Defendants' conduct set forth in this Count, the United States has suffered actual damages in the hundreds of millions of dollars, with the exact amount to be determined at trial.

COUNT TWO

(California False Claims Law, Cal. Gov. Code § 12650 *et seq*.)

122. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

123. Based on the foregoing allegations, the Defendants are liable under Cal. Gov. Code §12650 *et seq*.

COUNT THREE

(Colorado Medicaid False Claims Act, Col.Rev.Stat.25.5-4-303.5through 25.5-4-310 (2010) .)

124. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

125. Based on the foregoing allegations, the Defendants are liable under the Colorado Medicaid False Claims Act, Col.Rev.Stat.25.5-4-303.5 through 25.5-4-310 (2010).

COUNT FOUR

(Connecticut Gen. Stat. § 17b-301b (2010))

126. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

127. Based on the foregoing allegations, the Defendants are liable under Conn. Gen. Stat. § 17b-301b (2010).

COUNT FIVE

(Delaware False Claims & Reporting Act, 6 Del.C. §1201 *et seq*.)

128. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

129. Based on the foregoing allegations, the Defendants are liable under the Delaware False Claims & Reporting Act, 6 Del.C. §1201 *et seq*.

COUNT SIX

(District of Columbia False Claims Act, D.C. Code § 2-308.14 *et seq*.)

130. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

131. Based on the foregoing allegations, the Defendants are liable under the District of Columbia False Claims Act, D.C. Code § 2-308.14 *et seq*.

COUNT SEVEN

(Florida False Claims Act, Fla. Stat. §§ 68-081-68.09)

132. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

133. Based on the foregoing allegations, the Defendants are liable under Florida False Claims Act, Fla. Stat. §§ 68-081-68.09.

COUNT EIGHT

(Georgia State False Medicaid Claims Act, Georgia Code, Title 49, Ch. 4, Art. 7B)

134. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

135. Based on the foregoing allegations, the Defendants are liable under the Georgia State False Medicaid Claims Act, Georgia Code, Title 49, Ch. 4, Art. 7B.

COUNT NINE

(Hawaii False Claims Law, HRS § 661-21 *et seq*.)

136. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

137. Based on the foregoing allegations, the Defendants are liable under the Hawaii False Claims Law, HRS § 661-21 *et seq*.

COUNT TEN

(Illinois Whistleblower Reward & Protection Act, 740 ILCS 175/1 *et seq*.)

138. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

139. Based on the foregoing allegations, the Defendants are liable under the Illinois Whistleblower Reward & Protection Act, 740 ILCS 175/1 *et seq*.

COUNT ELEVEN

(Indiana False Claims & Whistleblower Protection Law, Ind. Code § 5-11-5.5.-1 *et seq*. (2005))

140. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

141. Based on the foregoing allegations, the Defendants are liable under the Indiana False Claims & Whistleblower Protection Law, Ind. Code § 5-11-5.5-1 *et seq*.

COUNT TWELVE

(Louisiana Qui Tam Action Act, La. R.S. 46:438:3 *et seq*.)

142. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

143. Based on the foregoing allegations, the Defendants are liable under the Louisiana Qui Tam Action Act, La. R.S. 46:438:3 *et seq*.

COUNT THIRTEEN

(Maryland False Health Claims Act, Md. Health-Gen. Code Ann. §§ 2-601 through 2-611(2010))

144. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

145. Based on the foregoing allegations, the Defendants are liable under the Maryland False Health Claims Act, Md. Health-Gen. Code Ann. §§ 2-601 through 2-611(2010).

COUNT FOURTEEN

(Massachusetts False Claims Law, ALM Ch. 12 § 5A-0 *et seq*.)

146. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

147. Based on the foregoing allegations, the Defendants are liable under the Massachusetts False Claims Law, ALM Ch. 12 § 5A-0 *et seq*.

COUNT FIFTEEN

(Michigan Medicaid False Claims Act, Mich. Code 400.601 *et seq*.)

148. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

149. Based on the foregoing allegations, the Defendants are liable under the Michigan Medicaid False Claims Act, Mich. Code 400.601 *et seq*.

COUNT SIXTEEN

(Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq*.)

150. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

151. Based on the foregoing allegations, the Defendants are liable under the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq*.

COUNT SEVENTEEN

(Montana False Claims Act, Mon. Code Ann. § 17-8-401 *et seq*.)

152. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

153. Based on the foregoing allegations, the Defendants are liable under the Montana False Claims Act, Mon. Code Anno. § 17-8-401 *et seq*.

COUNT EIGHTEEN

(Nevada Submission of False Claims to State or Local Government Act,
Nev. Rev. Stat. Ann. § 357.010 *et seq*.)

154. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

155. Based on the foregoing allegations, the Defendants are liable under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. § 357.010 *et seq*.

COUNT NINETEEN

(New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq*.)

156. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

157. Based on the foregoing allegations, the Defendants are liable under the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq*.

COUNT TWENTY

(New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq*.)

158. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

159. Based on the foregoing allegations, the Defendants are liable under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq*.

COUNT TWENTY-ONE

(New York False Claims Act, NY State Fin. Law, Art. 13)

160. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

161. Based on the foregoing allegations, the Defendants are liable under the New York False Claims Act, NY State Fin. Law, Art. 13.

COUNT TWENTY-TWO

(North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq*.)

162. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

163. Based on the foregoing allegations, the Defendants are liable under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq*.

COUNT TWENTY-THREE

(Oklahoma Medicaid False Claims Act, 63 Okla. St. § 5053.1 *et seq*. (2011))

164. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

165. Based on the foregoing allegations, the Defendants are liable under the Oklahoma Medicaid False Claims Act, 63 Okla. St. § 5053.1 *et seq*. (2011).

COUNT TWENTY-FOUR

(Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq*. (2010))

166. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

167. Based on the foregoing allegations, the Defendants are liable under the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq*. (2010).

COUNT TWENTY-FIVE

(Tennessee Medicaid False Claims Act, 71-5-181 through 71-5-185)

168. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

169. Based on the foregoing allegations, the Defendants are liable under the Tennessee Medicaid False Claims Act, 71-5-181 through 71-5-185.

COUNT TWENTY-SIX

(Texas False Claims Act, Texas Human Resources Code, § 36.002 *et seq*.)

170. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

171. Based on the foregoing allegations, the Defendants are liable under the Texas False Claims Act, Texas Human Resources Code, § 36.002 *et seq*.

COUNT TWENTY-SEVEN

(Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq*.)

172. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

173. Based on the foregoing allegations, the Defendants are liable under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq*.

COUNT TWENTY-EIGHT

(Wisconsin False Claims for Medical Assistance Act, Wis. Stat. § 20.931)

174. Plaintiff re-alleges Paragraphs 1 through 114, inclusive.

175. Based on the foregoing allegations, the Defendants are liable under the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. § 20.931.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff David M. Kester prays for the following relief:

1. On Counts One through Twenty-Eight, judgment for the United States or the State, as applicable, against the Defendants in an amount equal to three times the damages the federal or state plaintiff government, respectively, has sustained because of the Defendants' actions, plus a civil penalty of $11,000 for each violation;

2. On Counts One through Twenty-Eight, an award to the Relator of the maximum allowed under the federal or state law under which suit is brought by the Relator on behalf of the federal or state plaintiff, respectively;

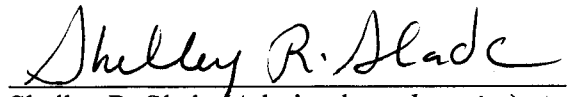
3. Against the Defendants, attorneys' fees, expenses and costs of suit; and

4. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands that this matter be tried before a jury.

Respectfully submitted,



Shelley R. Slade (Admitted *pro hac vice*)
Robert L. Vogel (SDNY Bar No. RV1527)
Janet L. Goldstein (Admitted *pro hac vice*)
VOGEL, SLADE & GOLDSTEIN, LLP
1718 Connecticut Avenue, NW, 7th Floor
Washington, D.C. 20009
Tel. 202-537-5900; E-mail: sslade@vsg-law.com

Attorneys for David M. Kester

Dated: April 18, 2013

CERTIFICATE OF SERVICE

On April 18, 2013, I caused copies of the foregoing First Amended Complaint, along with Appearances of Counsel for Janet Goldstein and Shelley Slade, to be served on the United States and all of the State plaintiffs by sending them by certified U.S. mail, postage prepaid and return receipt requested, to each of the persons listed below:

The Honorable Eric Holder
U.S. Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

The Honorable Preet Bharara
United States Attorney
U.S. Attorney's Office for the
Southern District of New York
86 Chambers Street
New York City, NY 10007

The Honorable Kamala D. Harris
Attorney General
Attorney General's Office
California Department of Justice
P.O. Box 944255
Sacramento, CA 94244-2550

The Honorable John Suthers
Attorney General
Office of the Attorney General
for the State of Colorado
Ralph L. Carr Colorado Judicial Center
1300 Broadway, 10th Floor
Denver, CO 80203

The Honorable George Jepsen
Attorney General
Office of the Attorney General
for the State of Connecticut
55 Elm Street
Hartford, Connecticut 06141

The Honorable Beau Biden
Attorney General of the State of Delaware
Delaware Department of Justice
Carvel State Office Bldg.
820 N. French Street
Wilmington, DE 19801

The Honorable Irvin B. Nathan
Attorney General
Office of the Attorney General
for the District of Columbia
441 4th Street, NW
Washington, DC 20001

The Honorable Pam Bondi
Attorney General
Office of Attorney General
for the State of Florida
The Capitol PL-01
Tallahassee, FL 32399-1050

Mr. Jeff Atwater
Chief Financial Officer of the State of Florida
Office of the Chief Financial Officer
Florida Department of Financial Services
200 East Gaines Street
Tallahassee, FL 32399

The Honorable Sam Olens
Attorney General
Office of the Attorney General
for the State of Georgia
40 Capitol Square, SW
Atlanta, GA 30334

The Honorable David M. Louie
Attorney General of the State of Hawaii
Department of the Attorney General
425 Queen Street
Honolulu, HI 96813

The Honorable Lisa Madigan
Attorney General
Office of the Attorney General
for the State of Illinois
Springfield Main Office
500 South Second Street
Springfield, IL 62706

The Honorable Greg Zoeller
Attorney General
Office of the Attorney General
for the State of Indiana
Indiana Government Center South
302 W. Washington Street, 5th Floor
Indianapolis, IN 46204

The Honorable James D. Caldwell
Attorney General
Office of the Attorney General
for the State of Louisiana
P.O. Box 94005
Baton Rouge, LA 70804

The Honorable Douglas F. Gansler
Attorney General
Office of the Attorney General
for the State of Maryland
200 St. Paul Place
Baltimore, MD 21202

The Honorable Martha Coakley
Attorney General of the
Commonwealth of Massachusetts
Office of the Attorney General
One Ashburton Place
Boston MA 02108

The Honorable Bill Schuette
Attorney General of the State of Michigan
Department of Attorney General
P.O. Box 30212
Lansing, MI 48909

The Honorable Lori Swanson
Attorney General of the State of Minnesota
Minnesota Attorney General's Office
1400 Bremer Tower
445 Minnesota Street
St. Paul, MN 55101

The Honorable Tim Fox
Attorney General of the State of Montana
Montana Department of Justice
P.O. Box 201401
Helena, MT 59620-1401

The Honorable Catherine Cortez Masto
Attorney General
Office of the Attorney General
for the State of Nevada
100 North Carson Street
Carson City, Nevada 89701-4717

The Honorable Jeffrey S. Chiesa
Attorney General
Office of the Attorney General
for the State of New Jersey
P.O. Box 080
Trenton, NJ 08625

The Honorable Peter Kilmartin
Attorney General
Office of the Attorney General
for the State of Rhode Island
150 S. Main Street
Providence, RI 02903

The Honorable Gary King
Attorney General
Office of the Attorney General
for the State of New Mexico
P.O. Drawer 1508
Santa Fe, NM 87504-1508

The Honorable Robert E. Cooper, Jr.
Attorney General and Reporter
Office of the Attorney General and Reporter
for the State of Tennessee
P.O. Box 20207
Nashville, TN 37202-0207

The Honorable Eric T. Schneiderman
Attorney General
Office of the Attorney General
for the State of New York
The Capitol
Albany, NY 12224-0341

The Honorable Greg Abbott
Attorney General
Office of the Attorney General
for the State of Texas
PO Box 12548
Austin, TX 78711-2548

The Honorable Roy Cooper
Attorney General
North Carolina Department of Justice
114 W. Edenton Street
Raleigh, NC 27603

The Honorable Kenneth T. Cuccinelli, II
Attorney General
Office of the Attorney General
for the Commonwealth of Virginia
900 E. Main Street
Richmond, VA 23219

The Honorable E. Scott Pruitt
Attorney General
Office of the Attorney General
for the State of Oklahoma
313 NE 21st Street
Oklahoma City, OK 73105

The Honorable J.B. Van Hollen
Attorney General of the State of Wisconsin
Wisconsin Department of Justice
P.O. Box 7857
Madison, WI 53707-7857

And by regular U.S. mail (postage prepaid) addressed as follows:

Li Yu, AUSA
U.S. Attorney's Office
Southern District of New York
86 Chambers Street
New York City, NY 10007

Rebecca Martin, AUSA
U.S. Attorney's Office
Southern District of New York
86 Chambers Street
New York City, NY 10007

Christopher Y. Miller, Esq.
Special Assistant Attorney General
Medicaid Fraud Control Unit
Office of the Attorney General
120 Broadway, 12th Floor
New York, NY 10271-0007

Laurie Oberembt, Esq.
Commercial Litigation Branch
U.S. Dept. of Justice, Civ. Div.
P.O. Box 261
Benjamin Franklin Station
Washington, D.C. 20044

Kerry Muldowney Ascher, Esq.
Assistant Attorney General
Civil Medicaid Fraud Division
P.O. Box 12548
Austin, TX 78711-2548

Ellen London, AUSA
U.S. Attorney's Office
Southern District of New York
86 Chambers Street
New York City, NY 10007

Shelley R. Slade (Admitted *pro hac vice*.)